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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,428	01/12/2004	Roberto Pedros	2331CON2 (203-2539CON2)	9696
Covidien 60 Middletown Avenue North Haven, CT 06473	7590 10/12/2011		EXAMINER TYSON, MELANIE RUANO	
			ART UNIT 3773	PAPER NUMBER
			MAIL DATE 10/12/2011	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/755,428	Applicant(s) PEDROS ET AL.	
	Examiner MELANIE TYSON	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 18,29-34 and 36-42 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 18,29-34 and 36-42 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

This action is in response to the applicant's amendment received 05 August 2011. The amendments made to the claims do not place the application in condition for allowance for the reasons set forth below. Claims 1-17, 19-28, and 35 remain cancelled. New claims 26-42 have been added.

Response to Arguments

Applicant's arguments filed 05 August 2011 with respect to claims 18 and 36-39 have been fully considered but they are not persuasive. The applicant argues that Tay fails to disclose the forceps are connected to the sleeve or that the forceps are adapted to longitudinally move from a first longitudinal closed position to a second longitudinal open position upon movement of the sleeve relative to the shaft. However, it is the examiner's position that Tay's sleeve, elongated shaft, and jaw members are all considered "connected" together to form the device. Furthermore, the individual components are not bonded or glued together. Therefore, it is the examiner's position that the sleeve is capable of longitudinal movement relative to the elongate shaft and upon such movement, the jaw members are also capable of a longitudinal movement as claimed. Therefore, the rejection of claims 18 and 36-39 over Tay and Kuehn is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18, 36-39, and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims require "at least one of the jaw members includes a tissue contacting surface" and "a recess." It is unclear as to how the vascular opening is fused closed with one tissue contacting surface and how the jaws maintain a closed low-profile position with one recess. **Furthermore, claims 18, 36-39, and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.** The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. At the time the application was filed the applicant failed to describe an embodiment containing one tissue contacting surface and one recess. Therefore, the limitations as claimed are considered new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 18 and 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tay et al. (U.S. Patent No. 5,507,744 - cited on 1449 dated 1/12/04) and Kuehn et al. (U.S. Patent No. 6,165,183).

Tay discloses an apparatus capable of substantially closing a vascular opening (see entire document) comprising a housing including a flange (32) and a sleeve (38) having proximal and distal ends and a longitudinal axis (for example, see Figure 1), an elongated shaft (41) at least partially disposed in the housing, a tissue engaging member (14) disposed adjacent the distal end of the housing (via deployment member 8) and being longitudinally and reciprocally movable relative to the housing to engage tissue (for example, see Figure 15A), two jaw members (50, 50) positioned adjacent the tissue engaging member and being movable independently thereof that close and capable of seizing vascular tissue (for example, see Figure 15), the jaw members each including planar tissue contacting surfaces formed of conductive material (distal surfaces that engage the tissue), and an energy source connected to the tissue contacting surfaces to facilitate transmission of energy to the tissue to thereby thermally fuse the opening (for example, see column 11, lines 34-67), wherein the sleeve is

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capable of longitudinal movement relative to the elongate shaft and upon such movement, the jaw members are also capable of a longitudinal movement as claimed. Tay fails to disclose the tissue engaging member may comprise two hooks or J-shaped configurations disposed in general diametrical opposed relation in the advanced position, wherein the engaging members are composed of a shape memory material such that they are adapted to resume the hook or J-shaped configuration when unstressed.

Kuehn discloses an apparatus capable of substantially closing a vascular opening (see entire document) comprising a housing (126) and at least two tissue engaging members (470, 472) being adjacent the distal end of the housing (for example, see Figure 22) and being longitudinally, reciprocally, and radially outwardly movable relative to the housing to engage tissue to assist in applying a fastener thereto (for example, see column 10, lines 4-14), each having a distal segment (480, 482) arranged in a general hook or J-shaped configuration being disposed in general diametrical opposed relation and generally curving away from the longitudinal axis when in an advanced position (for example, see Figure 22), wherein the engaging members have sharpened ends (for example, see column 10, lines 4-14). The substitution of one known element (Kuehn's tissue engaging members) for another (Tay's engaging member) would have been obvious to one of ordinary skill in the art at the time of the invention since the substitution of the tissue engaging members would have yielded predictable results, namely, providing a means for effectively engaging tissue.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18, 29-34, and 36-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,248,124.

Although the conflicting claims are not identical, they are not patentably distinct from each other because some of the claims of the patent "anticipate" some of the claims of the application and some of the application claims would have been obvious over the patent claims. Both inventions require a housing, tissue engaging members [tissue everting members; note that the everting members inherently have a deployment member in order to perform the recited deploying function] that move between jaw members [jaw members disposed about the everting members], wherein the jaw

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members move between open and closed positions, an elongated shaft having recesses [camming surface], and a conductive attachment member [electrode; note: in which the inwardly extending attachment as recited in the application claims forms a cooperating "camming surface" as recited in the patent claims]. Accordingly, the application claims are not patentably distinct from the patent claims. Here, the more specific patent claims (i.e., specifically requiring the attachment be an "electrode" for closing the opening) encompass the broader application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

With further respect to claim 20, it is well known in the art to use spring members with actuators, for example, clip appliers, in order to bias the jaws of the device into either an open position or a closed position. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the '124 invention with a spring member to bias the jaw members closed. Doing so would yield a simplified device requiring only a single input from the user to the actuator to open and close (or operate) the jaws.

With further respect to claims 29 and 35, providing medical devices with lumens or slots for tracking over a guidewire is well known in order to minimize damage to healthy tissue while inserting the device and tracking the device to the proper position within the body. Therefore, it would have been obvious to one having ordinary skill in

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the art at the time the invention was made to provide the elongated shaft of the '124 invention with a guidewire lumen or slot in order to be able to track the device over a properly positioned guidewire within the body, thus facilitating proper placement within the body while reducing the risk of damaging healthy tissue.

Claims 18, 29-34, and 36-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,676,685 B2.

Although the conflicting claims are not identical, they are not patentably distinct from each other because some of the claims of the patent "anticipate" some of the claims of the application and some of the application claims would have been obvious over the patent claims. Both inventions require a housing, tissue engaging members having a deployment member and move between jaw members [jaw members disposed about the everting members], wherein the jaw members move between open and closed positions, an elongated shaft having recesses [camming surface], and a conductive attachment member [thermal transmitting portion or electrode; note: in which the inwardly extending attachment as recited in the application claims forms a cooperating "camming surface" as recited in the patent claims]. Accordingly, the application claims are not patentably distinct from the patent claims. Here, the more specific patent claims (i.e., specifically requiring the attachment be a "thermal transmitting portion" or an "electrode" for closing the opening) encompass the broader application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the

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specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

With further respect to claim 20, it is well known in the art to use spring members with actuators, for example, clip applicers, in order to bias the jaws of the device into either an open position or a closed position. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the '685 invention with a spring member to bias the jaw members closed. Doing so would yield a simplified device requiring only a single input from the user to the actuator to open and close (or operate) the jaws.

With further respect to claims 29 and 35, providing medical devices with lumens for tracking over a guidewire is well known in order to minimize damage to healthy tissue while inserting the device and tracking the device to the proper position within the body. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the elongated shaft of the '685 invention with a guidewire lumen in order to be able to track the device over a properly positioned guidewire within the body, thus facilitating proper placement within the body while reducing the risk of damaging healthy tissue.

Claims 18, 29-34, and 36-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 7,252,666 B2.

Although the conflicting claims are not identical, they are not patentably distinct from each other because some of the claims of the patent "anticipate" some of the claims of the application and some of the application claims would have been obvious over the patent claims. Both inventions require a housing, tissue engaging members [tissue everting members; note that the everting members inherently have a deployment member in order to perform the recited deploying function], jaw members that move between open and closed positions, an elongated shaft having recesses [camming surface], and a conductive attachment member [electrode; note: in which the inwardly extending attachment as recited in the application claims forms a cooperating "camming surface" as recited in the patent claims]. Accordingly, the application claims are not patentably distinct from the patent claims. Here, the more specific patent claims (i.e., specifically requiring the attachment be an "electrode" for closing the opening) encompass the broader application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

With further respect to claim 20, it is well known in the art to use spring members with actuators, for example, clip appliers, in order to bias the jaws of the device into either an open position or a closed position. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the '666 invention with a spring member to bias the jaw members closed. Doing so

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would yield a simplified device requiring only a single input from the user to the actuator to open and close (or operate) the jaws.

With further respect to claims 29 and 35, providing medical devices with lumens or slots for tracking over a guidewire is well known in order to minimize damage to healthy tissue while inserting the device and tracking the device to the proper position within the body. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the elongated shaft of the '666 invention with a guidewire lumen or slot in order to be able to track the device over a properly positioned guidewire within the body, thus facilitating proper placement within the body while reducing the risk of damaging healthy tissue.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 8-7 (IFP).

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, Corrine McDermott, at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Melanie Tyson/
Primary Examiner, Art Unit 3773
October 5, 2011